

Amendments to the Specification

Please replace the paragraph beginning at line 3 of page 25 as follows:

FIG. 7 schematically illustrates the method for implanting the S-ICD of the present invention. An incision 31 is made in the left anterior axillary line approximately at the level of the cardiac apex. This incision location is distinct from that chosen for S-ICD placement and is selected specifically to allow both canister location more medially in the left inframammary crease and lead positioning more posteriorly via the introducer set (described below) around to the left posterior axillary line lateral to the left scapula. That said, the incision can be anywhere on the thorax deemed reasonably by the implanting physician although in the preferred embodiment, the S-ICD of the present invention will be applied in this region. A subcutaneous pathway 33 is then created medially to the ~~inframammary~~ inframammary crease for the canister and posteriorly to the left posterior axillary line lateral to the left scapula for the lead.

Please replace the paragraph beginning at line 19 of page 25 as follows:

The S-ICD canister 11 is then placed subcutaneously at the location of the incision or medially at the subcutaneous region at the left ~~inframammary~~ inframammary crease. The subcutaneous electrode 13 is placed with a specially designed curved introducer set 40 (see FIG. 8). The introducer set comprises a curved trocar 42 and a stiff curved peel away sheath 44. The peel away sheath is curved to allow for placement around the rib cage of the patient in the subcutaneous space created by the trocar. The sheath has to be stiff enough to allow for the placement of the electrodes without the sheath collapsing or bending. Preferably the sheath is made out of a biocompatible plastic material and is perforated along its axial length to allow for it to split apart into two sections. The trocar has a proximal handle 41 and a curved shaft 43. The distal end 45 of the trocar is tapered to allow for dissection of a subcutaneous path 33 in the patient. Preferably, the trocar is cannulated having a central Lumen 46 and terminating in an opening 48 at the distal end. Local anesthetic such as lidocaine can be delivered, if necessary, through the lumen or through a curved and elongated needle designed to

anesthetize the path to be used for trocar insertion should general anesthesia not be employed. The curved peel away sheath 44 has a proximal pull tab 49 for breaking the sheath into two halves along its axial shaft 47. The sheath is placed over a guidewire inserted through the trocar after the subcutaneous path has been created. The subcutaneous pathway is then developed until it terminates subcutaneously at a location that, if a straight line were drawn from the canister location to the path termination point the line would intersect a substantial portion of the left ventricular mass of the patient. The guidewire is then removed leaving the peel away sheath. The subcutaneous lead system is then inserted through the sheath until it is in the proper location. Once the subcutaneous lead system is in the proper location, the sheath is split in half using the pull tab 49 and removed. If more than one subcutaneous electrode is being used, a new curved peel away sheath can be used for each subcutaneous electrode.

Please replace the paragraph beginning at line 20 of page 57 as follows:

A “spade” shaped electrode 236 is depicted in Figure 23A. The distal end of the spade shaped electrode also generally follows the outline of the rounded distal end 234 of the canister housing 220. As the spade shaped electrode 236 moves proximally along the length of the canister housing 220, the conductive surface terminates in a rounded proximal end. Similar to the thumbnail embodiment described above, the spade shaped electrode’s conductive surface is generally contained within the distal end 234 of the canister housing 220. In alternate embodiments, the spade shape electrode’s conductive surface may extend proximally further within the canister housing 220. In yet another spade shaped electrode [[234]] 236 embodiment, the margins of the spade shaped electrode’s conductive surface refrain from following the exact rounded contour of the canister housing 220, but substantially form a spade shaped configuration.

Please replace the paragraph beginning at line 11 of page 75 as follows:

Extending distally beyond the shoulder region 232 is the distal head [[234]] 224 of the distal housing member 230. The distal head [[234]] 224 is the distal termination

point of the duckbill-shaped S-ICD canister 220. The distal head ~~[[234]]~~ 224 includes a generally rounded end. In one embodiment, illustrated in Figure 23B, the distal head ~~[[234]]~~ 224 has a width greater than the width at a location within the shoulder region 232 of the distal housing member 230. In alternative embodiments, the distal head's width is equal to or less than the width at any point in the shoulder region 232 of the distal housing member 230, as illustrated in 23A.

Please replace the paragraph beginning at line 21 of page 75 as follows:

The length of the duckbill-shaped S-ICD canister 220 may depend highly upon the shape and size of the distal housing member 230. In particular embodiments, the duckbill-shaped S-ICD canister 220 is approximately 30 centimeters long or less. In alternative embodiments, the duckbill-shaped S-ICD canister 220 is approximately 10 centimeter or less. In particular embodiments, the length of the duckbill-shaped S-ICD canister 220 may be curved, or alternatively, or a portion of the length (i.e., the shoulder region 232 and distal head ~~[[234]]~~ 224) are curved.

Please replace the paragraph beginning at line 7 of page 77 as follows:

In certain embodiments of the present invention, the electronic components (e.g., circuitry, batteries and capacitors) of the S-ICD canister 220 are generally absent from the distal housing member 230. As such, the depth of the distal housing member 230 may be greatly reduced. In these embodiments, a depth of approximately 1 millimeter may be obtained at the distal head ~~[[234]]~~ 224 of the duckbill-shaped S-ICD canister 220.

Please replace the paragraph beginning at line 15 of page 77 as follows:

The duckbill-shaped distal housing member 230 enhances navigation during canister implantation. The distal head ~~[[234]]~~ 224 of the distal housing member 230 is blunt at its end to reduce trauma suffered to surrounding tissue during the S-ICD canister's advancement or during chronic implantation. Similarly, the narrower distal

head ~~[[234]]~~ 224 (width-wise and depth-wise) is easier to control during the advancement procedure. The smaller distal head ~~[[234]]~~ 224 also enables a physician to navigate the smaller and more compact tissues adjacent to the sternum, which a larger head might otherwise find unobtainable. Moreover, the narrower distal head ~~[[234]]~~ 224 may be advanced to a location in close proximity to the patient recipient's heart 218 without concern of distorting or stressing the skin in the left parasternal region.